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(54) Title: AN ORTHOPAEDIC JOINT PROSTHESIS

(57) Abstract: An orthopaedic joint prosthesis comprises a first joint component and a second joint component. Each of the components is formed from a metal body and has a bearing surface which engages the corresponding bearing surface of the other component when the prosthesis is implanted. Each of the metal bodies has a ceramic coating applied to it at the bearing surface, the coating comprising a chromium compound and being at least about 5 μm thick. The coatings which can be different, for example so that the difference between the hardnesses of the materials of the coatings which are applied to the first and second joint components is less than about 5000 MPa. Preferably, the metal from which at least one of the first and second joint components is made has a modulus of at least about 150 GPa.

AN ORTHOPAEDIC JOINT PROSTHESIS

This invention relates to an orthopaedic joint prosthesis, which comprises a first joint component and a second joint component, each having a bearing surface which engages the corresponding bearing surface of the other component when the prosthesis is implanted.

Orthopaedic joint prostheses are known for replacement of natural joints such as a hip, knee, ankle and shoulder joint. Joint replacement generally involves removal of tissue from each of the articulating bones of the joint, and implantation of prosthesis components in the bones.

It is important that wear of the components of an artificial joint is minimised because wear debris can give rise to adverse physiological reactions. The selection of the materials for the joint components is made in such a way that wear is minimised, and also to ensure that the physiological reaction to such wear debris as is created is minimised.

It is common for a joint prosthesis to comprise components whose mating articulating surfaces comprise a metal and a polymer respectively (a "metal-on-polymer" joint). For example, the bearing surface on one of the components might comprise a cobalt-chrome-molybdenum alloy and the corresponding bearing surface on the other component might comprise a high molecular weight polyethylene. The surfaces of both components are finished so that they are smooth. During articulation of the joint, the polymeric component is subject to gradual wear, forming fine particles of the polymer.

Attempts have been made to form joint prostheses in which both of the articulating surfaces are manufactured from metals (a "metal-on-metal" joint). Even with very fine finishing to produce smooth bearing surfaces, wear in such prostheses cannot be avoided. The wear inevitably gives rise to the formation of metal particles. The wear characteristics of metal prosthesis components have been modified by application of ceramic coatings. An advantage that arises from use of a ceramic coating is that the greater hardness that is available allows wear to be reduced. Ceramic materials which have been used for such applications include titanium nitride and diamond-like carbon. Titanium nitride is

particularly favoured as a coating material for use on prosthesis components that are made from titanium because of the compatibility of the materials of the component body and the coating.

Difficulties have been encountered when attempting to create thick ceramic coatings on joint prosthesis components. The resulting components have been found to fail by cohesive failure of the coating. The maximum thickness of applied ceramic coatings has therefore been restricted to 2 to 3 μm. This has the disadvantage that, with use over an extended period, such a coating can wear to the extent that underlying metal is exposed. This has particular disadvantages when the component is formed from titanium because of the high susceptibility of titanium to wear.

The present invention provides an orthopaedic joint prosthesis in which each of the articulating prosthesis components has a metal body which has a ceramic coating applied to it at the bearing surface, the coating comprising a chromium compound and being at least 5 μm thick.

Accordingly, in one aspect, the invention provides an orthopaedic joint prosthesis, which comprises a first joint component and a second joint component, each being formed from a metal body and having a bearing surface which engages the corresponding bearing surface of the other component when the prosthesis is implanted, in which each of the metal bodies has a ceramic coating applied to it at the bearing surface, the coating comprising a chromium compound and being at least about 5 μm thick.

The prosthesis of the invention has the advantage that the susceptibility to failure due to cohesive failure of the coating can be reduced compared with prostheses in which bearing surfaces are provided by materials other than ceramic chromium compounds. This advantage is available, notwithstanding the greater thickness of the coatings compared with thin coatings as are used conventionally, for example with thicknesses of no more than 2 to 3 μm. This property is believed to arise from characteristics of the chromium compounds. The advantage arising from the lower susceptibility to cohesive failure can offset slightly

reduced hardness (and therefore potentially slightly increased wear rates) compared with certain other ceramic materials that are used to coat prosthesis bearing surfaces.

The ability to provide thick ceramic coatings in the prosthesis of the present invention has the advantage that the prosthesis is able to accommodate initial wear as the bearing surfaces of the components conform to one another. Small mis-matches in the shapes of the bearing surfaces of articulating components can give rise to initial localised wear of 1 to 3 μm. This can account for the entire thickness of conventional thin coatings.

Preferably, the thickness of the coating is at least about 6 μm, more preferably at least about 7 μm, especially at least about 8 μm, for example about 10 μm or more. The thickness of the coating will generally be less than about 25 μm, for example less than about 20 μm, or less than about 15 μm.

The chromium compounds which are used to provide the coatings can include one or more of chromium oxide, chromium nitride, chromium carbonitride and chromium carbide. The nitride and carbonitride are preferred.

Preferably, the difference between the hardnesses of the materials of the coatings which are applied to the first and second joint components is less than about 5000 MPa, more preferably less than about 2500 MPa, especially less than about 1000 MPa. It is particularly preferred that the hardnesses of the materials of the coatings is approximately the same. However, it is envisaged that different chromium compounds can be used on the articulating surfaces of two prosthesis components. For example, the bearing surface of one component might be coated with CrN and the corresponding bearing surface of the other component might be coated with CrCN.

Preferably, the materials of the coatings which are applied to the first and second joint components are the same.

Preferably, the metal which is used for the body of at least one of the components, preferably each of the components, has a modulus of at least about 150 GPa, more

preferably at least about 175 GPa, especially at least about 200 GPa. The use of a high modulus metal can reduce failure of the bond between the material of the bearing surface and the metal.

Examples of metals which can be used for the body include cobalt chrome based alloys, titanium alloys, and certain stainless steels. Preferably, the metal from which at least one of the first and second joint components is made is an alloy which includes chromium as a component element. It is an advantage of the present invention that a ceramic coating can be applied to a metal prosthesis component which is formed from a chromium based alloy, with enhanced adhesive interactions between the coating and the alloy of the body. It is particularly preferred that the metal from which at least one of the first and second joint components is made is a cobalt chromium molybdenum alloy, in particular an alloy which satisfies ASTM F-1537. The use of such alloys in orthopaedic joint prostheses is well established. It gives rise to advantages because of its hardness and low susceptibility to wear. According to the present invention, a prosthesis component formed from a chromium based alloy can be provided with a ceramic coating to increase wear resistance yet further, with strong adhesive interactions between the coating and the body. Furthermore, it appears that if, after use for a long period, the chromium based ceramic coating wears through and the alloy is exposed, the hard characteristics of the alloy mean that the component is not then subject to high wear rates as is the case for components in which the body is made from titanium.

Either of both of the components can be made in a plurality of parts which are formed from different materials. For example, when the joint prosthesis is for replacement of a hip joint, the femoral component can comprise separable stem and head parts which are formed from different materials. The bearing surface which articulates with a corresponding bearing surface on the acetabular component, and on which the ceramic coating is provided, will be on the head part. Alternatively or in addition, the acetabular component of a hip joint prosthesis can comprise separable shell and liner parts which are formed from different materials. The bearing surface which articulates with a corresponding bearing surface on the femoral component and on which the ceramic coating is provided will be on the liner part.

Preferably, the surface roughness of the coatings, as measured using conventional surface profilometer apparatus, which are applied to the first and second joint components is not more than about 0.05 μm (R_a), more preferably not more than about 0.02 μm (R_a), especially not more than about 0.01 μm (R_a). Preferably, the surface roughness is not more than about 0.1 μm (R_{pm}), more preferably not more than about 0.04 μm (R_{pm}). It is an advantage of the use of ceramic materials in the joint prosthesis of the present invention that they can conveniently be finished with such smooth surface properties by readily accessible surface finishing techniques using conventional techniques and commercially available equipment.

The present invention can be implemented in joints such as a hip, knee, ankle and shoulder joints, as well as joints in fingers, toes, wrists and elbows. For example, when the invention is implemented in a hip joint, the first component can comprise the head part of the femoral component, and the second component can comprise the cup part of the acetabular component. When the invention is implemented in a knee joint, the first component can comprise the femoral component and the second component can comprise the tibial component (which might include a meniscus component which can be moved relative to the part that is implanted in the tibia).

Generally, the coating will only be applied to the body of the component in the region of the bearing surface which articulates with the bearing surface of the other component of the joint.

Preferably, the coating is applied to the bearing surfaces by a vapour deposition technique. It is particularly preferred to use an evaporative physical vapour deposition technique. An example of suitable deposition equipment is available from IonBond AG, of Olten, Switzerland, such as for example the cathodic arc coating system sold under the trade mark PVD-3344. This uses a water cooled stainless steel cylindrical chamber of diameter 84 cm and height 112 cm which contains nine 5.4 kW arc sources.

The invention will now be illustrated with reference to examples.

COATING TECHNIQUE

Parts are coated using an IonBond 3344 arc evaporative PVD coating system available from IonBond AG, Industriestrasse 211, CH-4601 Olten, Switzerland. Parts are prepared for coating by cleaning using widely available aqueous detergents and then drying using hot air. The parts are mounted within the coating chamber on a fixture which allows the parts to be manipulated. The fixture for convex components such as the head of a femoral component of a hip joint prosthesis allows double rotation planetary motion. The fixture for concave components such as the cup of an acetabular component allows single rotation, with the mouth of the cup facing outwards towards the evaporation sources. The minimum distance between the parts and the evaporation sources is 180 mm.

The coating chamber is evacuated to a typical starting pressure of 2×10^{-5} mtorr. A part to be coated is then conditioned using a glow discharge in a mixture of argon and hydrogen. This is followed by a short bombardment with ions of chromium released by the evaporation sources and accelerated by a negative voltage of about -1000 V applied to the part. Deposition is undertaken at a chamber pressure of 48 mtorr of nitrogen gas (99.999% purity) with a negative voltage of about -300 V applied to the part.

The thickness of the coatings that are applied to the parts is at least 10 μm.

TEST RESULTS

Parts were coated using the technique described above and tested for wear rates and ion concentrations. The parts were femoral and acetabular components of a hip joint prosthesis, formed from a cobalt chrome molybdenum alloy. The femoral components had a spherical head with a diameter of 28 mm. After coating the bearing surfaces of the femoral and acetabular components with a 10 μm thick layer of ceramic material, the radial clearance between the bearing surface was 30 μm. Each of the bearing surfaces was finished to a surface roughness R_a of 0.02 μm.

Femoral and acetabular components of a hip joint prosthesis were prepared with ceramic coatings on the bearing surfaces of TiN, CrN and CrCN. The parts were tested in a hip simulator (of the kind referred to in J Eng Med 215 H 119-121 (2000)) which reproduces loads and motions during a normal walking cycle. Calf serum (25% (v/v)) was used to lubricate the bearing surfaces of the components during the tests. Wear volumes were determined by gravimetric analysis. The levels of metal ions from the prosthesis component bodies were determined by atomic absorption spectroscopy. The tests were performed with exposed (uncoated) metal bearing surfaces on both components, TiN coatings on the bearing surfaces of both components, CrN coatings on the bearing surfaces of both components, and CrCN coatings on the bearing surfaces of both components.

Figure 1 shows mean wear rates following wear tests using a hip joint simulator.

Figure 2 shows ion concentrations measured in joint serum lubricants following tests using the hip joint simulator.

The levels of wear and of ion concentration in the serum after two million walking cycles was significantly less for each of the coated samples than for the uncoated metal sample. The volume of wear debris that was produced from the three sets of coated components (measured in mm^3 per million cycles) after two million cycles did not vary significantly, and was less than about 0.1 mm^3/million cycles in each case (compared with about 1.3 mm^3/million cycles for the uncoated metal control). The CrN and CrCN coated components produced only small nanometre size particles, while the titanium nitride coated components produced both small nanometre size particles as well as larger shards consistent with the surface damage.

After five million cycles, the CrN and CrCN coated components showed a thirty six fold reduction in wear rate compared to the metal on metal control. No damage was found to the CrN and CrCN coatings in these longer term tests. The five million cycles test could not be completed for the TiN coated components because of the surface damage caused by cohesive failure of the coatings.

Both CrN and CrCN show substantial reductions in wear and ion release compared with uncoated metal joint prosthesis components. These materials can be applied as thick coatings which are stable on prolonged testing and do not appear to be susceptible to cohesive failure as exhibited by production of shards. The predicted time to wear through the thick coatings appears to be greater than 50 years.

Separate *in vitro* cell culture studies of the wear particles for CrN and CrCN show them to be at least tenfold less toxic than cobalt chrome wear debris at equivalent volume concentrations. CrN and CrCN bearing surfaces provide extremely low wear, low ion release and low biological activity.

CLAIMS:

1. An orthopaedic joint prosthesis, which comprises a first joint component and a second joint component, each being formed from a metal body and having a bearing surface which engages the corresponding bearing surface of the other component when the prosthesis is implanted, in which each of the metal bodies has a ceramic coating applied to it at the bearing surface, the coating comprising a chromium compound and being at least about 5 μm thick.

2. A joint prosthesis as claimed in claim 1, in which the coating comprises at least one of chromium nitride, chromium carbonitride and chromium carbide.

3. A joint prosthesis as claimed in claim 1, in which the thickness of the coating is at least about 8 μm.

4. A joint prosthesis as claimed in claim 1, in which the difference between the hardnesses of the materials of the coatings which are applied to the first and second joint components is less than about 5000 MPa.

5. A joint prosthesis as claimed in claim 1, in which the materials of the coatings which are applied to the first and second joint components are the same.

6. A joint prosthesis as claimed in claim 1, in which the metal from which at least one of the first and second joint components is made has a modulus of at least about 150 GPa.

7. A joint prosthesis as claimed in claim 1, in which the metal from which at least one of the first and second joint components is made is an alloy which includes chromium as a component element.

8. A joint prosthesis as claimed in claim 5, in which the metal from which at least one of the first and second joint components is made is a cobalt chromium molybdenum alloy.

9. A joint prosthesis as claimed in claim 1, in which the surface roughness (R_a) of the coatings which are applied to the first and second joint components is not more than about 0.05 μm.

10. A joint prosthesis as claimed in claim 1, in which the first component comprises the head part of the femoral component, and the second component comprises the cup part of the acetabular component of a hip joint prosthesis.

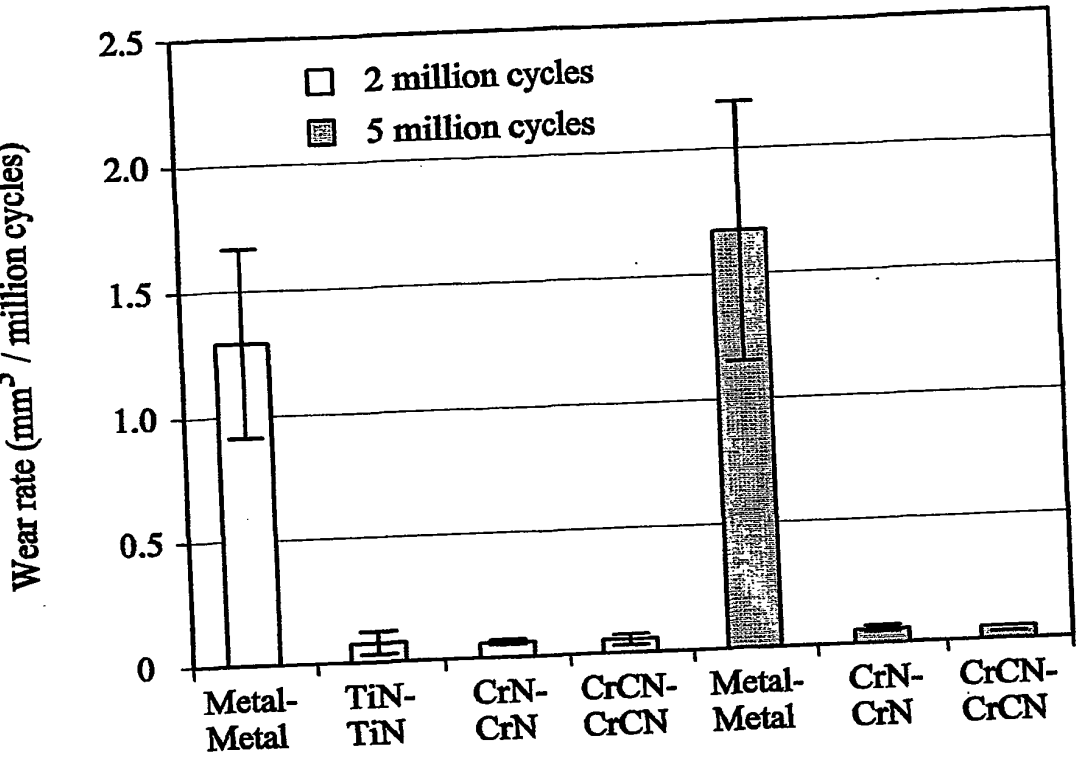

FIG. 1

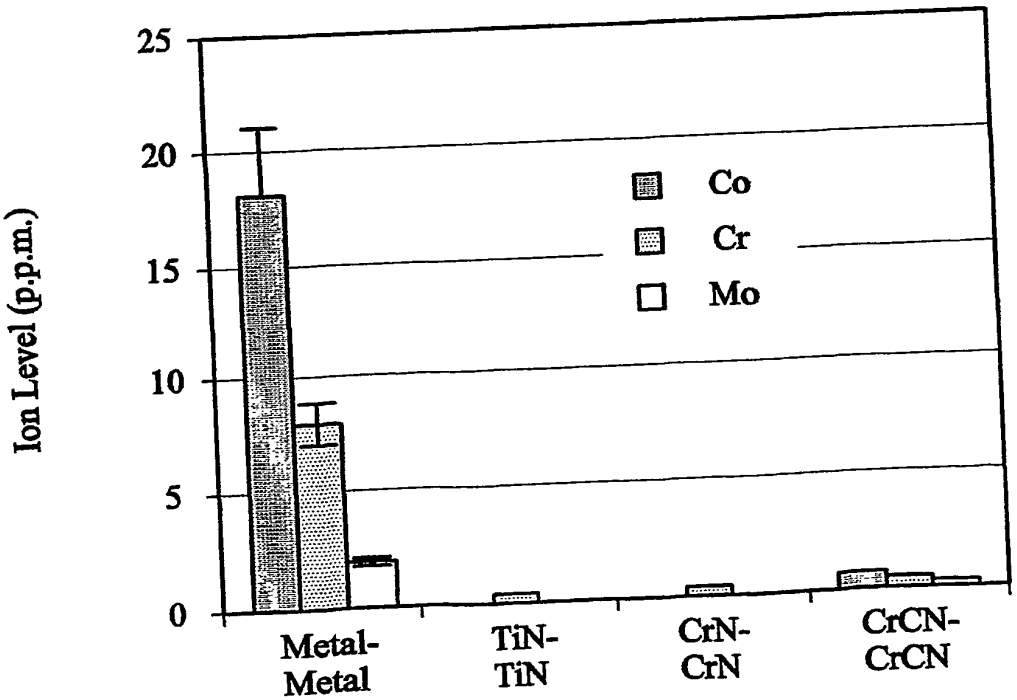

FIG. 2

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/GB 02/03146

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/30 A61L27/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 821 922 A (HUBIN) 4 February 1998 (1998-02-04) column 2, line 5 - line 18 column 4, line 39 - line 45; claim 9; figures	1-3,5,7, 8,10
X A	US 5 308 412 A (SHETTY) 3 May 1994 (1994-05-03) column 6 column 7, line 56 -column 8, line 11; claims 5,7,16,20,21; figures	1,2,7,8, 10 3,4
A	FR 2 413 078 A (SEROLE) 27 July 1979 (1979-07-27) page 3, line 9 - line 10 page 3, line 27 - line 37; claims 1,5; figures	1,2,6,10

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Klein, C

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INTERNATIONAL SEARCH REPORT

Intel ıal Application No
PCT/GB 02/03146

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	GB 2 186 000 A (TADANOBU OKUBO) 5 August 1987 (1987-08-05) abstract; claim 1	2

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INTERNATIONAL SEARCH REPORT

information on patent family members

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